

NCT 03403491				
Statistical analysis plan Appendix 1	date: 26-Jun-2019			
Protocol	www.clinicaltrials.gov registry no. NCT 03403491			
Version	2-Aug-17			
Amendment 01	20-Dec-18			
Demographic data (for Randomised & Treated datasets)				
Variable	data format	data presentation	Statistical comparison	Statistical test used
Date of birth	date	descriptive	none	
Age	n (years); calculated (informed consent-date of birth)	descriptive; mean +/- SD, min, max	check for treatment order effect (Treated dataset)	?
gender	number male/female	frequency, absolute, percentage, histogram	check for treatment order effect (Treated dataset)	?
ethnicity	number black/white/Asian/other	frequency, absolute, percentage, histogram	check for treatment order effect (Treated dataset)	?
primary cause of haemodialysis	number glomerular/diabetes/hypertension/hereditary/drug toxicity/other	frequency, absolute, percentage, histogram	check for treatment order effect (Treated dataset)	?
date 1st ever haemodialysis	date	descriptive	none	
time since 1st ever haemodialysis	n (years); calculated (informed consent-date 1st ever dialysis)	descriptive; mean +/- SD, min, max	check for treatment order effect (Treated dataset)	?
usual duration haemodialysis	minutes	descriptive; mean +/- SD, min, max	none	
comorbidities	number diabetes/hypertension/cardiovascular disease/congestive heart failure/peripheral vascular disease/neurologic/vision impairment/other	frequency, absolute, percentage, histogram	check for treatment order effect (Treated dataset)	?
vascular access modality	number permacath/arteriovenous fistula/arteriovenous graft/central venous catheter/other	frequency, absolute, percentage, histogram	none	
usual prescribed haemodialysis sessions/week	number	frequency, absolute, percentage, histogram	none	
on antihypertensive therapy	number yes/no	frequency, absolute, percentage, histogram	check for treatment order effect (Treated dataset)	?
number of antihypertensive therapies	number per patient	frequency, absolute, percentage, histogram	none	
classes of antihypertensive	number beta-blocker, calcium channel blocker, ACE inhibitor, angiotensin receptor blocker, diuretic, combination, other	frequency, absolute, percentage, histogram	none	
body mass index	number	descriptive; mean +/- SD, min, max	none	
Primary endpoint (engagement; Treated dataset)				
Variable (in protocol)	data format	data presentation	Statistical comparison	Statistical test used
patients asked to take part	number	descriptive, count	none	
patients giving informed consent	number	descriptive, count	none	
patients downloading pMp	number	descriptive, count	none	
patients using pMp at least once	number	descriptive, count	none	
patients using pMp >once	number	descriptive, count	none	
frequency of use of pMp	number of days used/number of days in pMp period	descriptive; mean +/- SD, min, max	none	
date interval informed consent vs. download	number of days	descriptive; mean +/- SD, min, max	none	
date interval download vs. first use	number of days	descriptive; mean +/- SD, min, max	none	
frequency of use of pMp (any use)	number of days used/number of days in pMp period	descriptive; mean +/- SD, min, max	none	
frequency of weight recorded on pMp	number of days recorded/number of days in pMp period	descriptive; mean +/- SD, min, max	check for treatment order effect; even balance of randomisation of sequences in >75% adherent group suggests treatment order effect unlikely	?
frequency of BP recorded on pMp	number of days recorded/number of days in pMp period	descriptive; mean +/- SD, min, max	check for treatment order effect	?
frequency of symptoms recorded on pMp	number of days recorded/number of days in pMp period	descriptive; mean +/- SD, min, max	none	
frequency of fluid intake recorded on pMp	number of days recorded/number of days in pMp period	descriptive; mean +/- SD, min, max	none	

patient questionnaire number	number of patients providing response/number of patients starting pMp	descriptive, count	none	
patient questionnaire responses	number of responses in each category of 6 questions	descriptive, categorical, count, histogram	none	
Secondary endpoints (clinic data)	impact of patientMpower on haemodialysis and symptoms (Treated & >75% adherent datasets)			
Variable (in protocol)	data format	data presentation	Statistical comparison	Statistical test used
proportion of haemodialysis sessions with ultrafiltration rate ≤ 10 mL/kg/h	categorical: number of sessions meeting endpoint/number of sessions	count sessions in which endpoint achieved, categorise as yes/no; assign to period	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
average ultrafiltration rate (mL/kg/h)	number	mean, (all sessions in a period) SD, min, max, assign to period	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
average ultrafiltration volume/session (mL)	number	mean, (all sessions in a period) SD, min, max, assign to period	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
average ultrafiltration volume/session (mL)	slope of change over time/patient	value vs. time plot, assign to period (graph/patient)	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
proportion of haemodialysis sessions with IDWG $\leq 4\%$	categorical: number of sessions meeting endpoint/number of sessions	count sessions in which endpoint achieved, categorise as yes/no; assign to period	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
average IDWG (%)	number	mean, (all sessions in a period) SD, min, max, assign to period	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
absolute IDWG (kg)	number	mean, (all sessions in a period) SD, min, max, assign to period	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
absolute IDWG (kg)	slope of change over time/patient	value vs. time plot, assign to period (graph/patient)	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	
pre-dialysis weight (clinic)	number	mean, (all sessions in a period) SD, min, max, assign to period	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
pre-dialysis weight (clinic)	slope of change over time/patient	value vs. time plot, assign to period (graph/patient)	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
post-dialysis weight (clinic)	number	mean, (all sessions in a period) SD, min, max, assign to period	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
post-dialysis weight (clinic)	slope of change over time/patient	value vs. time plot, assign to period (graph/patient)	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
pre-dialysis SBP (clinic)	number	mean, (all sessions in a period) SD, min, max, assign to period	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
pre-dialysis DBP (clinic)	number	mean, (all sessions in a period) SD, min, max, assign to period	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
pre-dialysis SBP (clinic)	slope of change over time/patient	value vs. time plot, assign to period (graph/patient)	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
pre-dialysis DBP (clinic)	slope of change over time/patient	value vs. time plot, assign to period (graph/patient)	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
post-dialysis SBP (clinic)	number	mean, (all sessions in a period) SD, min, max, assign to period	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
post-dialysis DBP (clinic)	number	mean, (all sessions in a period) SD, min, max, assign to period	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
post-dialysis SBP (clinic)	slope of change over time/patient	value vs. time plot, assign to period (graph/patient)	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
post-dialysis DBP (clinic)	slope of change over time/patient	value vs. time plot, assign to period (graph/patient)	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
medication adherence	number of days adherence reported/number of days in pMp period	count, mean, SD, min, max	none	
unplanned haemodialysis sessions	number of unplanned sessions	count, allocate to period: run-in, sham or pMp	none	
clinic dry weight [pre-dialysis weight (kg) -ultrafiltration goal volume (L)]	number	mean, (all sessions in a period) SD, min, max, assign to period	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
clinic dry weight [pre-dialysis weight (kg) -ultrafiltration goal volume (L)]	slope of change over time/patient	value vs. time plot, assign to period (graph/patient)	run-in vs. active vs. sham within-subject analysis ; test for treatment order effect	?
Secondary endpoints (patient-reported data)	impact of patientMpower on haemodialysis and symptoms (Treated dataset)			
Variable (in protocol)	data format	data presentation	Statistical comparison	

symptoms (any reported) on \geq one day	number of patients reporting any symptom \geq once	descriptive, count	none	
max number of symptoms reported on \geq one day	number of patients reporting 0, 1, 2, 3, 4, 5 or 6 symptoms on \geq one day	descriptive, categorical, count, histogram	none	
symptoms (muscle cramp) reported on \geq one day	number of patients reporting this symptom \geq once	descriptive, count	none	
symptoms (muscle cramp) worst severity	number of patients reporting this symptom none, 1-2, 3-4 or \geq 4 times/day \geq once	descriptive, categorical, count, histogram	none	
symptoms (muscle cramp) severity over time	Assign severity score to symptom (not at all =0, 1, 2 /d= 1, 2-4/d = 2, \geq 4/d =3); trend over time	value vs. time plot (graph/patient)	none	
symptoms (feeling washed out) reported on \geq one day	number of patients reporting this symptom \geq once	descriptive, count	none	
symptoms (feeling washed out) worst severity	number of patients reporting this symptom none, mild, moderate, severe \geq once	descriptive, categorical, count, histogram	none	
symptoms (feeling washed out) severity over time	Assign severity score to symptom (not at all =0, mild = 1, moderate = 2, severe =3); trend over time	value vs. time plot (graph/patient)	none	
symptoms (light-headedness) reported on \geq one day	number of patients reporting this symptom \geq once	descriptive, count	none	
symptoms (light-headedness) worst severity	number of patients reporting this symptom none, mild, moderate, severe \geq once	descriptive, categorical, count, histogram	none	
symptoms (light-headedness) over time	Assign severity score to symptom (not at all =0, mild = 1, moderate = 2, severe =3); trend over time	value vs. time plot (graph/patient)	none	
symptoms (shortness of breath) reported on \geq one day	number of patients reporting this symptom \geq once	descriptive, count	none	
symptoms (shortness of breath) worst severity	number of patients reporting this symptom none, mild, moderate, severe \geq once	descriptive, categorical, count, histogram	none	
symptoms (shortness of breath) severity over time	Assign severity score to symptom (not at all =0, mild = 1, moderate = 2, severe =3); trend over time	value vs. time plot (graph/patient)	none	
symptoms (swollen ankles) reported on \geq one day	number of patients reporting this symptom \geq once	descriptive, count	none	
symptoms (swollen ankles) worst severity	number of patients reporting this symptom none, mild, moderate, severe \geq once	descriptive, categorical, count, histogram	none	
symptoms (swollen ankles) severity over time	Assign severity score to symptom (not at all =0, mild = 1, moderate = 2, severe =3); trend over time	value vs. time plot (graph/patient)	none	
symptoms (cough) reported on \geq one day	number of patients reporting this symptom \geq once	descriptive, count	none	
fluid intake reported on \geq one day	number of patients reporting fluid intake \geq once	descriptive, count	none	
maximum fluid intake	number of patients reporting small, medium or large fluid intake \geq once	descriptive, categorical, count, histogram	none	
fluid intake quantity over time	Assign score to amount (small =1, medium = 2, large =3); trend over time	value vs. time plot (graph/patient)	none	
Target weight	slope of change over time/patient	descriptive; value vs. time plot (target weight is as entered on pMp), graph/patient	none	
Target weight/dry weight	slope of change over time/patient	descriptive; value vs. time plot (target weight is as entered on pMp; dry weight from haemodialysis clinic data); graph/patient	none	
weight change vs. target weight	number of times in 0.00-1.99%, 2.00-3.49%, 3.50-4.49% and \geq 4.5% gain vs. target per patient (positive or negative)	descriptive, categorical, count, histogram (graph/patient & total patient population)	none	
weight change vs. target weight	slope of change over time/patient	descriptive; value vs. time plot (target weight is as entered on pMp), graph/patient	none	
SBP (seated)	number	descriptive, mean, SD, min, max of all values (per patient)	none	
SBP (seated)	slope of change over time/patient	descriptive; value vs. time plot, graph/patient	none	
DBP (seated)	number	descriptive, mean, SD, min, max of all values (per patient)	none	
DBP (seated)	slope of change over time/patient	descriptive; value vs. time plot, graph/patient	none	
Inferior vena cava data	variable	data format	Statistical comparison	Statistical test used
longitudinal diameter (mm)	number	descriptive, count, mean, SD, min, max; allocate to period (run-in, sham, active)		
transverse diameter (mm)	number	descriptive, count, mean, SD, min, max; allocate to period (run-in, sham, active)		

longitudinal diameter (mm)	slope of change over time/patient	value assigned to period (run-in, active, sham); graph/patient	run-in vs. active vs. sham within-subject analysis; test for treatment order effect; if none compare mean total population values per period	?
transverse diameter (mm)	slope of change over time/patient	value assigned to period (run-in, active, sham); graph/patient	run-in vs. active vs. sham within-subject analysis; test for treatment order effect; if none compare mean total population values per period	?
Collapsibility	50% collapsible on inspiration?	descriptive, categorical, count	run-in vs. active vs. sham within-subject analysis; test for treatment order effect; if none compare mean total population values per period	